THE RIGHT TO THE RESEARCH

For years, researchers at the Harvard School of Public Health have been sounding the alarm on the health dangers of microscopic particles in the air. An epidemiologic study of air pollution in six U.S. cities showed conclusively, these researchers say, that particles measuring less than 2.5 micrometers in diameter are some of the most toxic substances in the air. The Six Cities Study, as the work came to be known, has resulted in more than 100 scientific papers leading to a troubling conclusion: the tiny particles play a big role in supporting levels of air pollution that may be shortening people's life spans by as much as two years in the most polluted areas.

While the findings of the Six Cities Study have prompted serious debate for some time, it wasn't until this year that they ignited into full-blown controversy. The EPA, in announcing final rules designed to tighten ozone standards and reduce emissions of particles, stated that the stringent measures were necessary because research—in particular, the Harvard research—had shown how dangerous the particles are. The EPA gave industry four years to meet the new rules and estimated that it would cost industry about $6 billion.

Industry quickly organized to defend against this new governmental challenge, and came back with a compliance cost estimate of its own: $23 billion. And with the estimate came a demand to examine Harvard's data. Industrial interests argue that, because the Harvard research was funded by the government—and, thus, taxpayer dollars—the data are public property that should be made available for public review. When Harvard's researchers refused to release their raw data and accompanying analysis on the basis that much of it is confidential personal medical information, it touched off public, academic, and congressional debate on the issue of public access to federally funded research.

Reasons to Keep Secrets

Scientists are hesitant to release their data to the public for several reasons. The one cited most often is the need to protect the confidentiality of subjects and their personal information. Researchers argue that if the information subjects provide to researchers may become public, people will be less likely to participate in studies, thereby having a chilling effect on research.

Another reason given for not releasing data is the fear that parties with vested interests, such as industry, would interpret such data to support their own positions—because many scientists believe that by introducing enough variables into a data analysis you can make the data support any conclusion—rather than accepting the interpretation given by the study's authors. There's also a question of timing: if data are released prior to completion of the academic review process, they may distort the scientific process because often in the early stages of any research project there can be false leads or other problems that can be resolved later in the review process.

A third reason is competition among scientists. Researchers may withhold data, not wishing for other scientists to easily benefit from the fruits of their own scientific labors, or because they plan to build on the data in future research and do not want these future efforts undermined or extracted.

The argument that publicly funded researchers should provide access to data is based on the contention that the use of public dollars makes the data public property. Although there may be various reasons that various groups would like to see research data, the most vocal group has been industry, mainly because research, particularly in the health and environmental arenas, is often used as the basis of laws, rules, and policies that exact compliance costs.

Industry's argument for access may seem reasonable—Mary Nichols, EPA assistant

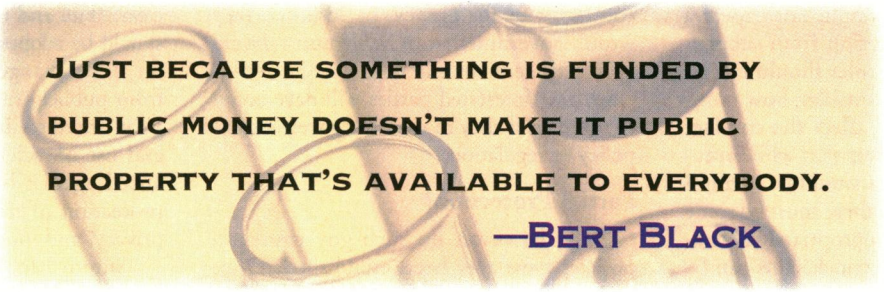
administrator for air and radiation, sent a letter to Harvard earlier this year asking the researchers to share their data. But the legal precedents relating to the issue of public access to federally funded research come down strongly, but not exclusively, on the side of scientific autonomy. In terms of data access, there's a big difference between work done by government agencies and work done by contractors. The Freedom of Information Act (FOIA) covers the work of all federal agencies, but it doesn't cover the work of contractors. In a 1980 U.S. Supreme Court decision, *Forsham v. Harris*, the justices decided that data from private organizations conducting research for the government are not subject to the FOIA, and, thus, do not have to be disclosed unless the contracting agency exercises its right to obtain the data from the contractor. Therefore, agencies could demand that the researchers they fund provide the raw data, but they don't often do it out of respect for the concept of scientific integrity. If such agencies don't demand the data, it doesn't have to be revealed to anyone.

"Just because something is funded by public money doesn't make it public property that's available to everybody," says Dallas attorney Bert Black, former chair of the American Bar Association's section on science and technology. "So the idea that scientific work should automatically be made available just doesn't ring true." However, facing the prospect of spending billions to meet the new air standards, industry tends to disagree. Industry wants a law that would require research contractees to provide their data to the contractor agencies.

A Case Study

A group calling itself the Air Quality Standards Coalition and representing some 600 predominantly industrial and automotive businesses has contended that industries affected by the new particulate standards should see the raw data for themselves. The coalition, along with other industry groups, has sought congressional action. Congressman Thomas Bliley (R-Virginia), who is chair of the House Commerce Committee, has taken up the issue and called for disclosure of the Harvard data.

Then things went a step further when freshman Congressman Robert Aderholt (R-Alabama), a member of the Appropriations Committee's Treasury–Postal Appropriations Subcommittee, tried to attach an amendment to a spending bill for the postal service and the treasury. The amendment called for all recipients of federal research money to disclose research results, "including all underlying data and supplementary details." Despite its inclusion of an exemption for materials that would constitute invasions of privacy, the amendment was defeated in committee, 34 to 19.



Harvard, meanwhile, had responded to the criticism by proposing an alternative: it would provide its raw data for a reanalysis to be completed by 1999 to the Health Effects Institute, a respected research institute that is funded by the EPA and industry, and located in Cambridge, Massachusetts. While industry generally lauded that effort, many claim it is not enough. Charles J. DiBona, president of the American Petroleum Institute, for instance, criticizes the EPA for not taking fuller responsibility in providing the data. "We are not attacking the [air quality] proposals as bad science," he says. "We are attacking them as bad policy, as actions that will leave the people of the nation worse off. We want the EPA to stop claiming that the agency is the helpless pawn of science. We want it to admit that its proposals represent moral and economic choices, and to debate them in that arena."

Even though the legislative effort failed, some lawmakers are still convinced that the Harvard–EPA flap has pointed out a problem that needs to be rectified. The Fiscal Year 1998 EPA appropriations bill includes language calling for an appropriation of $49.6 million for "a comprehensive, peer-reviewed, near- and long-term particulate matter research program." This bill has now passed Congress, and a conference report on the appropriation states that "conferees expect that all research data resulting from this funding will become available to the public, with proper safeguards for researchers' first right of publication, for scientific integrity, for individuals participating in studies, for proprietary commercial interests, and to prevent scientific fraud and misconduct."

Public Access Denied?

Although the Harvard issue has grown quieter in recent months, the general debate continues: should publicly funded research data be made public, and if so, what kind of data would be included and what kind of safeguards should be attached?

Joseph K. Alexander, deputy assistant administrator for science in the EPA's office of research and development, has organized an internal group to develop a policy on how data compiled by EPA scientists and grantees alike should be preserved for study. The absence of such a policy, in itself, is telling of the EPA's position on public access to publicly funded research by grantees. "My impression," says Alexander, "is that it's very ad hoc."

In Harvard's case, the EPA provided data to assist the researchers, but the primary funder of the Six Cities Study was the NIEHS. "Our position is that we're happy to provide any data in our possession," Alexander says. "But [with Harvard] we don't have control over the data." At the NIEHS, H.B. Matthews, chief of the chemical branch of the Environmental Toxicology Program (ETP), said that the general policy on release of data is much the same as at the EPA. "If we have a study being conducted under contract, the public does not have access to that information until the contractor submits it to us," he says. "We can't go the contractor and say, 'Give [a third party] the information.'" William C. Eastin, director of information systems for the ETP's toxicology operations branch, says that his office, too, only makes available the data that are in its possession. "If people want to see it, they can come in here and see it," he says. "We spread it out on the table and they can take a look at it."

Still, even though federal agencies tend to extend protection to their research grantees, and even though the Supreme Court has ruled that the data produced by those grantees are not covered by FOIA, that doesn't mean researchers enjoy carte blanche protection from ever revealing data. Black says that courts can subpoena research results even if those data are obtained as the result of confidentiality assurances. In an article that he wrote for the 6 March 1997 issue of the *New England Journal of Medicine*, Black described the experience of University of Chicago professor Arthur Herbst, who was forced to reveal confidential data from a study in which he identified high cancer

rates among children of women who had taken the drug DES. While requiring disclosure, the court did allow the litigants to agree on a method of disclosure that protected the identity of individual patients.

In that article, Black proposed that the Federal Rules of Civil Procedure be modified to provide a balance between complete scientific protection and compelled disclosure. "Scientists should not expect a blanket, absolute exemption from subpoena," he wrote, "but the rules should explicitly require judges to consider how compelled disclosure would affect the conduct of research." Black believes that while automatic availability of data would be harmful to the scientific process, there must be some mechanism to provide appropriately redacted data so that research conclusions can be properly validated.

Another frequently cited case, *Bunch v. Dow Chemical Co.*, involved a publicly funded grant recipient seeking confidentiality of research data on Reye's syndrome in the 1980s. The Centers for Disease Control and Prevention contracted with a research firm to conduct a study on the relationship between aspirin and Reye's syndrome. The contractor told parents of the patients with the syndrome that no identifying information would be released. The study confirmed an association between aspirin use and the disease and, predictably, product-liability suits were filed by the children's parents against aspirin manufacturers. A variety of interested parties, many of them the aspirin manufacturers themselves, sought access to the research data through FOIA. Since the data were in the possession of the contractor and, thus, not subject to FOIA disclosure, the only recourse for someone wanting to see it was to file a lawsuit, which is what one of the aspirin manufacturers did.

The end result of the litigation was a 1985 protective order that struck a balance between individuals' privacy and the company's need to review the data that had damaged its product's reputation. In a 25 December 1986 article in the *New England Journal of Medicine*, authors Joseph C. Connors and Bryan Jay Yolles, who are lawyers, and Seymour Grufferman, a Duke University Medical Center physician, detailed the Reye's syndrome litigation to illustrate that "policy making based on summarized research data frequently leads to legal controversies."

Because government-sponsored studies often lead to health policies and regulatory changes that prompt litigation, the authors recommended several alternatives. For instance, they wrote, when such studies lead to new health policies or regulations, the data supporting those decisions should be shared with all interested parties, regardless of whether they're in the hands of the contractor or the agency. In addition, they wrote, government research grants should be contingent on the contractee's acceptance that interested parties will have access to the data if they're used for governmental policy or regulation.

Partial Protection?

Clearly, however, no such governmental policies have ever been established. Once again, though, people are talking about it. Alexander says he believes that the federal government has an obligation to make publicly funded data available. "The question, though," he says, "is when? And through what process?"

Just as sources of information used in scientific research may deserve confidentiality, scientists deserve to not have their work rushed into public view prematurely, Alexander contends. Typically, good science entails peer review of research and publication in scientific journals, an often lengthy process that the drafters of the ill-fated disclosure amendment heard by the House Appropriations Committee didn't seem to care about. The amendment called for disclosure "not later than 90 days of the first public use of the research."

Speaking of the process of peer review and quality assurance, Alexander says, "If researchers know they have to provide the data before those are completed, there's a real time and resources impact." A requirement to disclose data early in the process puts pressure on the researchers and jeopardizes the time and effort they have put into the study. Also, he says, any emphasis on rapid disclosure is professionally risky for researchers. He says, "They'll be thinking, 'Am I putting my work and my career in jeopardy by providing the data?'" Nevertheless, says Alexander, "The scientific community has been moving in the direction where researchers don't sit on data."

Indeed, although a recently released two-year U.S. National Academy of Sciences study, *Bits of Power: Issues on Global Access to Scientific Data*, focuses on international exchange of electronic data, its conclusion is clear: "Full and open access to scientific data should be adopted as the international norm for the exchange of scientific data derived from publicly funded research. The public-good interests in full and open access to, and use of, scientific data need to be balanced against legitimate concerns for the protection of national security, individual privacy, and intellectual property."

Suresh Moolgavkar, an epidemiologist at the Fred Hutchinson Cancer Research Center in Seattle who has criticized the Six Cities Study, concedes that researchers deserve protection. "I think there are two points of view on this and they both have merit," he says. "The question is how do you resolve these reasonable concerns on both sides." One answer, he suggests, is more use of independent and reputable research centers like the Health Effects Institute for reanalysis of data. Another, he says, is establishment of mechanisms to ensure confidentiality of study subjects.

Ever since the postal service and treasury disclosure amendment was defeated in committee this past summer, the debate has been somewhat quieter in Washington, DC. Still, industry groups that are faced with footing a hefty bill for tighter air quality standards remain keenly interested in the issue of how to strike a balance between scientific autonomy and the public's right to know. "There is no legitimate reason why data cannot or should not be released," says Karen Kerrigan, president of the 40,000-member Small Business Survival Committee (SBSC), "especially when the research was funded by the taxpayers themselves." The SBSC and other business and industry groups have promised vigilant attention to achieving legislation that will provide that access. Many scientists, of course, will continue to seek to keep the data confidential as much as possible, at least until it's been peer-reviewed.

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—KAREN KERRIGAN

Richard Dahl